REMARKS

Applicant respectfully requests entry and consideration of Applicant's Response and Amendment to the Final Office Action filed April 11, 2008, and all papers accompanying that response, specifically the Statement Under 37 CFR 3.73(b) and the two Terminal Disclaimers. Accordingly, claims 1-7 and 9-17 as amended April 11, 2008, are pending.

Entry and consideration is also requested for Applicant's Appeal Brief filed August 7, 2008, and Applicant's Reply Brief filed December 11, 2008. The arguments and case law cited therein apply directly to the rejections and objections in the Final Office Action of February 11, 2008.

In addition, this RCE with its accompanying fee and submission serves to withdraw the Applicant's appeal to the Board of Patent Appeals and Interferences from the Final Office Action dated February 2, 2008, final rejection of claims 1-7 and 9-17. Notice to the Board will be sent under separate communication.

The following remarks and attached exhibit (Exhibit I) further provide for a proper submission pursuant to 37 C.F.R. § 1.114(a)(1) and consistent with patent office practice per MPEP § 706.07(h).

Applicant submits the following remarks and Exhibit I in further support of Applicant's previous arguments of record traversing the Final Office Action rejections that were premised on alleged inherent anticipation of the present claims by the cited publications in which pramlintide was administered to patients having diabetes in order to treat the diabetes by controlling blood sugar. In brief, Exhibit I demonstrates that weight loss was not observed in all patients who had diabetes, and in many cases were also obese, that were administered pramlintide specifically to treat their diabetes by controlling their blood sugar. Accordingly, a patient treated for control of blood sugar according to the cited art would not have necessarily and inevitably also achieved weight loss.

Exhibit I is a print out of a clinical Study Results web page http://clinicaltrials.gov/ct2/show/results/NCT00467649?show_out=2#outcome3 from the NIH-managed ClinicalTrials.gov website at which U.S. clinical trial results are reported. Exhibit I presents the Study Results of a clinical study entitled "A Study to Characterize Regimens of Basal Insulin Intensified With Either Symlin® or Rapid Acting Insulin in Patients With Type 2 Diabetes." This study was sponsored by Amylin Pharmaceuticals, Inc., the assignee of the present application. The study reports the clinical effects of the amylin analog pramlintide, for which SYMLIN is the brand name, on weight loss in patients with diabetes.

As indicated in Exhibit I, at page 1, pramlintide was administered at 120 micrograms twice a day (i.e. with major meals) to patients with diabetes and who were also taking insulin (Group A). The Examiner's attention is directed to Exhibit I, at pages 3-4, the results section entitled "Secondary Outcomes Measure: Proportion of Patients With no Weight Gain at Week 24." As reported in that section at page 4, the proportion of patients that did not gain weight (either lost weight or were weight neutral) with pramlintide treatment (i.e., Group A) was 46.4%, which indicates that 53.6% DID gain weight.

This evidence provides concrete support for the Applicant's previous arguments and cited case law demonstrating a lack of inherency in the cited art. As noted in the record, to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). The fact that a certain result or characteristic may be present in the prior art is not sufficient to establish the inherency—inherency may not be established by probabilities or possibilities. *Continental Can Co. USA, Inc., v. Monsanto Co., 948 F.2d 1264, 1268* (Fed Cir. 1991); *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Simply stated, it is not sufficient that a person following the teachings of the cited art sometimes obtains the claimed result—it must invariably happen. Accordingly, Applicant submits that the cited art does not inherently anticipate the claimed methods for the reasons already of record and further in view of the evidence submitted herewith. The specific rejections to which the above evidence and argument is applicable include those of Sections 26 and 27 of the Final Office Action asserting

double patenting, and Sections 33, 34, 35 and 36 asserting anticipation. Withdrawal of these rejections is respectfully requested.

In light of the enclosed remarks and the amendments and remarks in the entered submissions, Applicant respectfully requests reconsideration and withdrawal of all objections and rejections set forth in the Final Office Action of February 11, 2008.

Further, Applicants believe all claims presently under consideration to be in a condition for allowance and request issuance of a Notice of Allowance at the Examiner's earliest convenience.

Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicant encourages the Examiner to contact the undersigned to discuss any issues remaining.

Fees totaling $810.00 are believed due with this submission. However, if this calculation is incorrect, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Respectfully submitted,
AMYLIN PHARMACEUTICALS, INC.

Dated: 20 Oct. 09

Timothy E. Torchia
Registration No. 36,700

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A Study to Characterize Regimens of Basal Insulin Intensified With Either Symlin® or Rapid Acting Insulin in Patients With Type 2 Diabetes

This study has been completed.

Study NCT00467649 Information provided by Amylin Pharmaceuticals, Inc.
First Received: April 27, 2007 Last Updated: April 10, 2009 History of Changes

Study Type:	Interventional
Study Design:	Randomized, Open Label, Active Control, Parallel Assignment
Condition:	Type 2 Diabetes Mellitus
Interventions:	Drug: pramlintide acetate Drug: rapid acting insulin (Humalog® [insulin lispro], Novolog® [insulin aspart], or Apidra® [insulin glulisine]) Drug: basal insulin (Lantus® [insulin glargine], or Levemir® [insulin detemir])

Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA insulin: variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study
Group C (P2 SYMLIN)	Patients from Group A, who achieved HbA1c goal at Week 24, continued Phase 1 treatment during Phase 2
Group D (P2 SYMLIN+RA)	Patients from Group A, who did not achieve HbA1c goal at Week 24, continued phase 1 treatment and initiated RA insulin during Phase 2
Group E (P2 RA Insulin)	Patients from Group B, who achieved HbA1c goal at Week 24, continued Phase 1 treatment during Phase 2
Group F (P2 RA Insulin + SYMLIN)	Patients from Group B, who did not achieve HbA1c goal at Week 24, continued phase 1 treatment and initiated SYMLIN during Phase 2

Participant Flow for 2 periods

Period: Phase 1 (Intent-to-Treat Population)

	Group A (P1 SYMLIN)	Group B (P1 RA Insulin)	Group C (P2 SYMLIN)	Group D (P2 SYMLIN+RA)	Group E (P2 RA Insulin)	Group F (P2 RA Insulin + SYMLIN)
STARTED	56	56	0	0	0	0
COMPLETED	48	50	0	0	0	0
NOT COMPLETED	8	6	0	0	0	0
Adverse Event	2	0	0	0	0	0
Investigator Decision	1	0	0	0	0	0
Lost to Follow-up	2	4	0	0	0	0
Withdrawal of Consent	3	2	0	0	0	0

Period: Phase 2 (Intent-to-Treat Population)

	Group A (P1 SYMLIN)	Group B (P1 RA Insulin)	Group C (P2 SYMLIN)	Group D (P2 SYMLIN+RA)	Group E (P2 RA Insulin)	Group F (P2 RA Insulin + SYMLIN)
STARTED	0	0	17	31	14	36
COMPLETED	0	0	17	29	14	35
NOT COMPLETED	0	0	0	2	0	1
Lost to Follow-up	0	0	0	1	0	0
Protocol Violation	0	0	0	1	0	0
Withdrawal of Consent	0	0	0	0	0	1

Baseline Characteristics

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA Insulin: variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Baseline Measures

	Group A (P1 SYMLIN)	Group B (P1 RA Insulin)	Total
Number of Participants [units: participants]	56	56	112
Age [units: participants]			
<=18 years	0	0	0
Between 18 and 65 years	46	49	95
>=65 years	10	7	17
Age [units: years] Mean ± Standard Deviation	55.0 ± 11.35	53.6 ± 9.70	54.3 ± 10.53
Gender [units: participants]			
Female	22	19	41
Male	34	37	71
Region of Enrollment [units: participants]			
United States	56	56	112
Fasting Plasma Glucose [units: mg/dL] Mean ± Standard Deviation	155.1 ± 39.60	164.3 ± 49.61	159.7 ± 44.92
Fasting Serum Lipids [units: mg/dL] Mean ± Standard Deviation			
Total Cholesterol	167.53 ± 47.054	169.86 ± 49.121	168.70 ± 47.903
HDL	44.71 ± 11.893	41.77 ± 9.468	43.23 ± 10.790
LDL	89.15 ± 38.386	90.41 ± 34.114	89.78 ± 36.133
Triglycerides	174.13 ± 108.257	193.59 ± 159.508	183.95 ± 136.273
HbA1c [units: %] Mean ± Standard Deviation	8.19 ± 0.840	8.25 ± 0.816	8.22 ± 0.825
Waist Circumference [units: cm] Mean ± Standard Deviation	116.31 ± 15.427	117.15 ± 13.198	116.73 ± 14.297
Weight [units: Kg] Mean ± Standard Deviation	107.87 ± 21.893	103.46 ± 17.908	105.67 ± 20.032

Outcome Measures

Hide results for all outcome measures

1. **Primary Outcome Measure: The Proportion of Patients Achieving HbA1c <=7% at Week 24 With no Gain in Body Weight From Baseline and no Incidence of Severe Hypoglycemia**

Measure Type	Primary
Measure Title	The Proportion of Patients Achieving HbA1c <=7% at Week 24 With no Gain in Body Weight From Baseline and no Incidence of Severe Hypoglycemia
Measure Description	Comprehensive treatment endpoint assessing the achievment of glycemic control without weight gain and severe hypoglycemia. The patient must acheive each component of the endpoint to count towards the final percentage.
Time Frame	24 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 1 Intent-to-Treat LOCF. LOCF: If a treated patient has missing result value at week 24, then last observed value before week 24 and after baseline is carried forward to impute the week 24 value.

Reporting Groups

	Description

Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA Insulin: variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Measured Values

	Group A (P1 SYMLIN)	Gr B R Ins
Number of Participants Analyzed [units: participants]	56	5
The Proportion of Patients Achieving HbA1c <=7% at Week 24 With no Gain In Body Weight From Baseline and no Incidence of Severe Hypoglycemia [units: %]	30.4	1(

Statistical Analysis 1 for The Proportion of Patients Achieving HbA1c <=7% at Week 24 With no Gain In Body Weight From Baseline and no Incidence of Severe Hypoglycemia

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	0.0180

[1] Additional details about the analysis, such as null hypothesis and power calculation:
No text entered.

[2] Other relevant information, such as adjustments or degrees of freedom:
No text entered.

[3] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
No text entered.

2. Secondary Outcome Measure: **Proportion of Patients Achieving HbA1c <=7% at Week 24**

Measure Type	Secondary
Measure Title	Proportion of Patients Achieving HbA1c <=7% at Week 24
Measure Description	This is a component of the primary endpoint
Time Frame	24 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 1 Intent-to-Treat

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA Insulin: variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Measured Values

	Group A (P1 SYMLIN)	Group B (P1 RA Insulin)
Number of Participants Analyzed [units: participants]	56	56
Proportion of Patients Achieving HbA1c <=7% at Week 24 [units: %]	44.6	55.4

No statistical analysis provided for Proportion of Patients Achieving HbA1c <=7% at Week 24

3. Secondary Outcome Measure: **Proportion of Patients With no Weight Gain at Week 24**

Measure Type	Secondary
Measure Title	Proportion of Patients With no Weight Gain at Week 24
Measure Description	This is a component of the primary endpoint
Time Frame	24 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 1 Intent-to-Treat

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA Insulin: variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Measured Values

	Group A (P1 SYMLIN)	Group B (P1 RA Insulin)
Number of Participants Analyzed [units: participants]	56	56
Proportion of Patients With no Weight Gain at Week 24 [units: %]	46.4	14.3

No statistical analysis provided for Proportion of Patients With no Weight Gain at Week 24

4. Secondary Outcome Measure: **Proportion of Patients With a Severe Hypoglycemia Adverse Event**

Measure Type	Secondary
Measure Title	Proportion of Patients With a Severe Hypoglycemia Adverse Event
Measure Description	This is a component of the primary endpoint
Time Frame	24 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 1 Intent-to-Treat

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA Insulin: variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Measured Values

	Group A (P1 SYMLIN)	Group B (P1 RA Insulin)
Number of Participants Analyzed [units: participants]	56	56
Proportion of Patients With a Severe Hypoglycemia Adverse Event [units: %]	0.0	0.0

No statistical analysis provided for Proportion of Patients With a Severe Hypoglycemia Adverse Event

5. Secondary Outcome Measure: **Change in HbA1c From Baseline at Week 24**

Measure Type	Secondary
Measure Title	Change in HbA1c From Baseline at Week 24
Measure Description	No text entered.
Time Frame	24 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 1 Intent-to-Treat LOCF. LOCF: If a treated patient has missing result value at week 24, then last observed value before week 24 and after baseline is carried forward to impute the week 24 value

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA Insulin: variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Measured Values

	Group A (P1 SYMLIN)	Group B (P1 RA Insulin)
Number of Participants Analyzed [units: participants]	56	56
Change in HbA1c From Baseline at Week 24 [units: %] Least Squares Mean ± Standard Error	-1.11 ± 0.17	-1.27 ± 0.17

No statistical analysis provided for Change in HbA1c From Baseline at Week 24

6. Secondary Outcome Measure: **Change in Body Weight From Baseline at Week 24**

Measure Type	Secondary
Measure Title	Change in Body Weight From Baseline at Week 24
Measure Description	No text entered.
Time Frame	24 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 1 Intent-to-Treat LOCF. LOCF: If a treated patient has missing result value at week 24, then last observed value before week 24 and after baseline is carried forward to impute the week 24 value.

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA insulin: variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Measured Values

	Group A (P1 SYMLIN)	**Group B (P1 RA insulin)**
Number of Participants Analyzed [units: participants]	**56**	**56**
Change in **Body Weight From Baseline at Week 24** [units: kg] Least Squares Mean ± Standard Error	**0.02 ± 0.68**	**4.65 ± 0.68**

No statistical analysis provided for Change in Body Weight From Baseline at Week 24

7. Secondary Outcome Measure: **Change in Waist Circumference From Baseline**

Measure Type	Secondary
Measure Title	Change in Waist Circumference From Baseline
Measure Description	No text entered.
Time Frame	24 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 1 Intent-to-Treat LOCF. LOCF: If a treated patient has missing result value at week 24, then last observed value before week 24 and after baseline is carried forward to impute the week 24 value.

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA Insulin: variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Measured Values

	Group A (P1 SYMLIN)	**Group B (P1 RA Insulin)**
Number of Participants Analyzed [units: participants]	**53**	**56**
Change in Waist Circumference From Baseline [units: cm] Least Squares Mean ± Standard Error		
Change at Week 24	**-0.63 ± 0.87**	**2.17 ± 0.86**

No statistical analysis provided for Change in Waist Circumference From Baseline

8. Secondary Outcome Measure: **Change in Fasting Plasma Glucose From Baseline**

Measure Type	Secondary
Measure Title	Change in Fasting Plasma Glucose From Baseline
Measure Description	No text entered.
Time Frame	24 Weeks

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 1 Intent-to-Treat

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA Insulin; variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Measured Values

	Group A (P1 SYMLIN)	Group B (P1 RA Insulin)
Number of Participants Analyzed [units: participants]	45	50
Change in Fasting Plasma Glucose From Baseline [units: mg/dL] Mean ± Standard Error		
Change at Week 24	-29.0 ± 7.32	-37.8 ± 7.69

No statistical analysis provided for Change in Fasting Plasma Glucose From Baseline

9. Secondary Outcome Measure: **Fasting Serum Lipids Change From Baseline at Week 24**

Measure Type	Secondary
Measure Title	Fasting Serum Lipids Change From Baseline at Week 24
Measure Description	No text entered.
Time Frame	24 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 1 Intent-to-Treat

Reporting Groups

	Description
Group A (P1 SYMLIN)	SYMLIN treatment (120 mcg prior to major meals) was initiated on Day 1. Basal insulin was titrated throughout the study
Group B (P1 RA Insulin)	Rapid acting insulin (RA Insulin; variable dosing, titrated to optimize postprandial glucose control) was initiated at Week 4. Basal insulin was titrated throughout the study

Measured Values

	Group A (P1 SYMLIN)	Group B (P1 RA Insulin)
Number of Participants Analyzed [units: participants]	47	49
Fasting Serum Lipids Change From Baseline at Week 24 [units: mg/dL] Mean ± Standard Error		
Total Cholesterol	-1.81 ± 5.826	5.27 ± 4.649
HDL	1.11 ± 1.190	1.65 ± 1.075
LDL	2.36 ± 4.456	9.12 ± 3.865
Triglycerides	-26.96 ± 12.442	-31.98 ± 13.883

No statistical analysis provided for Fasting Serum Lipids Change From Baseline at Week 24

10. Secondary Outcome Measure: **Phase 2: Change in HbA1c at Week 36**

Measure Type	Secondary
Measure Title	Phase 2: Change in HbA1c at Week 36
Measure Description	No text entered.
Time Frame	36 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Phase 2 Intent-to-Treat

Reporting Groups

	Description
Group C (P2 SYMLIN)	Patients from Group A, who achieved HbA1c goal at Week 24, continued Phase 1 treatment during Phase 2
Group D (P2 SYMLIN+RA)	Patients from Group A, who did not achieve HbA1c goal at Week 24, continued phase 1 treatment and initiated RA insulin during Phase 2
Group E (P2 RA Insulin)	Patients from Group B, who achieved HbA1c goal at Week 24, continued Phase 1 treatment during Phase 2
Group F (P2 RA Insulin + SYMLIN)	Patients from Group B, who did not achieve HbA1c goal at Week 24, continued phase 1 treatment and initiated SYMLIN during Phase 2

Measured Values

	Group C (P2 SYMLIN)	Group D (P2 SYMLIN+RA)	Group E (P2 RA Insulin)	Group F (P2 RA Insulin + SYMLIN)
Number of Participants Analyzed [units: participants]	17	30	14	36
Phase 2: Change in HbA1c at Week 36 [units: %] Mean ± Standard Error				
Change From Baseline	-1.96 ± 0.238	-0.68 ± 0.174	-1.49 ± 0.189	-0.99 ± 0.157
Change From Week 24	0.14 ± 0.062	-0.23 ± 0.123	0.22 ± 0.097	0.07 ± 0.113

No statistical analysis provided for Phase 2: Change in HbA1c at Week 36

11. Secondary Outcome Measure: **Phase 2: Change in Body Weight at Week 36**

Measure Type	Secondary
Measure Title	Phase 2: Change in Body Weight at Week 36
Measure Description	No text entered.
Time Frame	36 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Phase 2 Intent-to-Treat

Reporting Groups

	Description
Group C (P2 SYMLIN)	Patients from Group A, who achieved HbA1c goal at Week 24, continued Phase 1 treatment during Phase 2
Group D (P2 SYMLIN+RA)	Patients from Group A, who did not achieve HbA1c goal at Week 24, continued phase 1 treatment and initiated RA insulin during Phase 2
Group E (P2 RA Insulin)	Patients from Group B, who achieved HbA1c goal at Week 24, continued Phase 1 treatment during Phase 2
Group F (P2 RA Insulin + SYMLIN)	Patients from Group B, who did not achieve HbA1c goal at Week 24, continued phase 1 treatment and initiated SYMLIN during Phase 2

Measured Values

	Group C (P2 SYMLIN)	Group D (P2 SYMLIN+RA)	Group E (P2 RA Insulin)	Group F (P2 RA Insulin + SYMLIN)
Number of Participants Analyzed [units: participants]	17	30	14	36
Phase 2: Change in Body Weight at Week 36 [units: kg] Mean ± Standard Error				
Change From Baseline	-0.80 ± 2.096	1.34 ± 0.933	3.90 ± 1.488	4.51 ± 0.761
Change From Week 24	0.69 ± 0.654	0.50 ± 0.303	0.44 ± 0.518	-0.86 ± 0.353

No statistical analysis provided for Phase 2: Change in Body Weight at Week 36

Reported Adverse Events

No Adverse Events Entered.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.
There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

Results Point of Contact:

Name/Title: Chief Medical Officer
Organization: Amylin Pharmaceuticals Inc
e-mail: clinicaltrials@amylin.com

No publications provided

Responsible Party:	Amylin Pharmaceuticals (Lisa Porter, MD, Study Director)
Study ID Numbers:	ACA401
Study First Received:	April 27, 2007
Results First Received:	April 10, 2009
Last Updated:	April 10, 2009
ClinicalTrials.gov Identifier:	NCT00467649 History of Changes
Health Authority:	United States: Institutional Review Board